GE Healthcare

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Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM (S) OF THESE ISSUES AND HOW TO ADDRESS THEM

February 9, 2007

To: **Director/Manager of Radiology**

Subject: **Product Safety Issues**

Affected Products: **OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System,**

Our records indicate that your facility has one or more of the following GEHC OEC products:

- OEC® 9800
- OEC® FluoroTrak 9800 Plus
- OEC® 9800 Plus
- OEC® 9800*MD* Motorized C-arm System

GE Healthcare has identified a potential safety issue with the systems listed above that have the following serial numbers: **89-1685, 89-2907, 89-2877, 89-2383, 89-3330, 82-7059-MH, 89-0247-RC, 89-0599, and 89-2987, 89-1001, 89-0972**

According to our records, the systems with the serial numbers listed above had the camera cover on the Image Intensifier replaced during a service call. The camera shield that was placed onto your system during this service call may not have the protective lead barrier as required. The lack of lead shielding may result in excessive scatter radiation exposure to the user and patient and is non compliant with CFR 21 Sec. 1020.32.

At this time users are advised to stop using the systems with the corresponding serial numbers listed above until the camera cover and shields are inspected /replaced.

Solution:

GE OEC will be contacting your facility in the immediate future to schedule the replacement of the camera shield on your system with an appropriate protective lead barrier.

Users are advised to stop using the unit until the camera cover/shield has been inspected and replaced if necessary.

GEHC OEC is working on inspecting all affected systems and replacing all affected camera covers/shields as soon as possible at no charge to your facility.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

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